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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/779,095	GUERET, JEAN-LOUIS	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-30 and 35-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-30 and 35-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 02/06/2009.

Claims 2-4, 31-34 have been canceled.

Claims 1, 5-30, 35-68 are pending and included in the prosecution.

The following rejections have been overcome by virtue of applicant's amendment and remarks:

The rejection of claim 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejection was discussed in details in the previous office action, and is maintained for reasons of record:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 66-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 66-68 recite the limitation "substantially constant thickness". Recourse to the specification does not disclose anywhere that the composite has substantially constant thickness. In paragraph 0022 of the published application, applicant disclosed that: "These two support layers can be of different roughnesses, porosities, or thicknesses so as to make two different types of application possible depending on which face is selected by the user." In paragraph 0062 applicant disclosed: "The support layers 12 and 13 can be of different thicknesses." In paragraph 0077 applicant disclosed: "The composite structure 40 of the embodiment shown in FIG. 4 comprises an adhesive matrix 41 sandwiched between two support layers 42 and 43 respectively constituted by a polyethylene film having a thickness of 40 micrometers (.mu.m) and by a hydrophilic non-woven cloth with a weight per surface area of 40 g/m.sup.2, made up of a mixture of polypropylene and viscose fibers". In paragraph 0085 applicant disclosed: "FIG. 7 shows a composite structure 70 comprising an adhesive matrix 71 sandwiched between support layers 72 and 73 of different thickness". Therefore, no disclosure whatsoever in the specification for "composite that has substantially constant thickness". In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Response to Arguments

3. Applicant's arguments filed 02/06/2009 have been fully considered but they are not persuasive. Applicant relies on figures 1-10 for support of the limitation of “constant thickness" and argues that the figures show composite structure having substantially constant thickness. Applicant argues that there is nothing in the specification that would indicate any of figures 1-10 depict merely a portion of an article.

In response to this argument, it is argued that figures 1-10 are only representation of the disclosed device and not the actual figures of the device. Additionally, the figures do not show any thickness and the "Description of the Drawing" does not describe thickness of the device. Therefore, the figures did not contemplate that the disclosed device has constant thickness. Additionally, nothing in the specification indicated that figures 1-10 depict the whole article.

The following new grounds of rejections are necessitated by applicant’s amendment:

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 5-11, 14-18, 27, 36-44, 47-52, 54-57, 59, 60, 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2186042 ('042).

The present claims 1, 54-56 are drawn to article comprising two non-adhesive layers, at least one of these layers is permeable to a solvent, and an adhesive layer disposed between the two non-adhesive layers and comprises adhesive and active agent that can be delivered upon wetting of the article, the non-adhesive layers define the outer surface of the article. Claim 27 is directed to conventional method of making the article that comprises the steps of coating the composition comprising the adhesive on the first non-adhesive layer, and then assembling the second non-adhesive layer.

CA '042 teaches cosmetic or skin-pharmaceuticals patch for controlled release of at least one cosmetic compound or skin pharmaceutically active on the skin. The patch comprises occlusive support layer and protective layer and polymer matrix enclosed in between the protective and the support layers. The polymer matrix consists of a hydrophobic polymer in which are scattered evenly particles of active compound and particles of at least one hydro-absorbent agent. The matrix is based on a silicone polymer or polyurethane. Such patches have structure consisting of several layers in the following order: a first layer is support layer, second layer is polymer matrix attached to the support layer containing the active compound, this layer can come directly in contact with the skin; possibly, to facilitate the fixing of the patch on the skin, a layer of a material adhesive applied to the surface of the reservoir/matrix layer and permeable to active compound; finally, a detachable layer of protection. The patch includes a perforated frame sheet of a non-woven natural or synthetic fibers and a net by natural or

synthetic fibers, and support layer made of a polymer chosen from among polyethylene high and low density, polypropylene, polyvinyl chloride, ethylene copolymers and acetate vinyl, polyester and polyurethanes. The reference teaches method of making the patch that reads on the method claimed by claim 27 comprising mixing the ingredients, and spreading the mixture with a blade in a layer 0.8 mm thick on a sheet of polyethylene with a thickness of 200 mu m, applying the nylon polyethylene net and applying a film of polyethylene of 30 mu m thick layer which is the support or occlusive patch, and it proceeded to calendering of the whole., thus providing a patch with an support occlusive layer and a self-adhesive reservoir layer composed of a polymer matrix silicone partially reticulate, and a layer of protection. (See example 1). Therefore, the polymer matrix is disclosed as being adhesive, and also disclosed as being between support layer and nylon polyethylene perforated net. (See claims 14-16, page 4 of the translation). The reference disclosed in the second full paragraph of page 6 that the polymer layer containing the drug can be self adhesive. (See page 3, claims 1-3 of the provided translation, and page 4). The active compounds are chosen from vitamin C, vitamin A, vitamin E, enzymes and antibiotics, and the hydro-absorbing agent is chosen from polyacrylates superabsorbent, polyvinyl alcohol, carboxyvinyl polymers, semi-synthetic derivative of cellulose, starches, guar gum, Arabian or adragante, casein, phytocolloides, cotton fibre and gelatin, all meet the limitation of claims 7 and 9. The hydro-absorbent particles are in the form of a freeze-dried powder possibly containing at least one active substance. The matrix further comprises powdered soy protein and wheat which read on polyamide powder claimed by claims 43 and 44 (See claims 8-11,

page 3 and page 6 of the translation). In contact with moisture from the skin (or possibly in the presence of water applied to the skin or shell layer) particles of hydro-absorbent react and then gradually release the particles of active compound, i.e. the active agent is released from the patch when the patch is wetted with water and contacted the skin as required by the generic claims, and claims 5, 6, 47-49, 65. (See page 5 of the translation). The reference teaches that the cosmetic compound or skin pharmaceutically asset is present in a proportion of between about 0.2 and 48% by weight and hydro-absorbing agent in a proportion of between about 0.1 and 30% by weight compared to the total weight of the matrix layer that read on the amounts claimed in claims 8 and 42 (See page 6). The hydro-absorbing agents are expected to be capable to absorb water and form a hydrogel, and that reads on the limitations of claims 36-41. The reference teaches middle adhesive matrix including polyurethane and silicone polymers that are expected to be able to permanently bond to the first and second layers.

Although the reference teaches three layers, two non-adhesive layers and at least one adhesive matrix, the reference does not explicitly teach the two non-adhesive layers defining an outer surface of the composite.

CA '042 teaches: 1) the occlusive layer non-adherent, that is not the removable protective layer; 2) adhesive matrix; and 3) net perforated layer embedded in the matrix, that means it is inside the adhesive matrix, and surrounded from above and below with the adhesive matrix. Therefore, the article disclosed by the reference comprises at least three layers wherein the adhesive matrix has in one side an occlusive non-adhesive

layer and non-adhesive perforated net on the other side. It has been held that reversal or rearrangement of parts was held to be an obvious expedient. *In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955); *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

Therefore, the present invention as whole, as claimed by claims 1, 5-11, 14-18, 27, 36-44, 47-52, 54-57, 59, 60, 65-68, is taught and is obvious over CA '042.

Response to Arguments

6. Applicant's arguments filed 02/06/2009 have been fully considered but they are not persuasive.

Independent claim 1:

Applicants argue that the "protective layer" disclosed by '042 patent cannot be permanently bonded to the adhesive matrix. If it were, the layer of protection would not be detachable. In what appears to be an alternative argument, the Office Action also alleged that a "nylon net" or "mesh" disclosed in the '042 patent, in the fourth paragraph

from the bottom of page 7, constitutes a second non-adhesive layer permanently bonded to the adhesive matrix. The '042 patent does not disclose, however, that an adhesive matrix is disposed between the nylon net and the occlusive support layer. It appears that the nylon net in the '042 patent is embedded in a matrix. If the nylon net is positioned in contact with the support layer, the matrix would not be between the nylon net and the occlusive support layer. There is no disclosure in the '042 patent that suggests the nylon net is placed in any other location. It appears that the matrix of the patch disclosed in the '042 patent is an outer, skin-contacting layer, and that the nylon net is embedded in the matrix and not adhered to the outer surface of the matrix. Thus, the '042 patent fails to disclose "at least one of the two non-adhesive layers being permeable to a solvent and defining an outer surface of the composite structure, the outer surface being configured to be placed into contact with the surface region," as recited in independent claim 1, as amended.

In response to this argument, it is the examiner position that the present claims are directed to product comprising 3 layers, and the three layers are disclosed by the CA '042: 1) the occlusive layer non-adherent, that is not the removable protective layer; 2) adhesive matrix; and 3) net perforated layer embedded in the matrix, that means it is inside the adhesive matrix, and surrounded from above and below with the adhesive matrix. Therefore, the article disclosed by the reference comprises three layers wherein the adhesive matrix has in one side an occlusive non-adhesive layer and non-adhesive perforated net on the other side. The claims do not exclude the presence another layers such as part of the adhesive matrix on the other side of the perforated net, nor require

more than one layer being non-adhesive. The elements of claim 1 are all disclosed by CA ‘042. The article disclosed by the reference is for skin contact as required by the present claims.

Independent Claims 27 and 54-56

Applicant hereby repeats the argument with regard to claim 1 as applicable to claims 27, 54, and 55. Therefore, the same response as for claim 1 is repeated hereby.

Independent Claim 68

Applicant argues that the '042 patent fails to disclose a composite structure having, among other things, "a substantially constant thickness," as recited in claim 68. The '042 patent discloses that the composite structure can be obtained by cutting the desired forms, which produces pinched edges. Since the composite structure in the '042 patent is disclosed to have pinched edges, the composite structure does not have a "substantially constant thickness," as required by claim 68.

In absence of clear disclosure regarding “substantially constant thickness”, the reference disclosure reads on claim 68.Speficially, the reference teaches only pinched edges, and this means the rest of the device, i.e. in the middle away from the edges, will have substantially constant thickness. Furthermore, no disclosure made by the reference that the thickness is not constant. Even with pinched edges, the reference teaches substantial constant thickness in absence of definition to the relative term “substantially”.

7. Claims 19-26, 28-30, 35, 45, 46, 53, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA '042 in view of US 5,350,581 ('581).

The teachings of CA '042 are previously discussed as set forth in this office action.

Although the teachings CA '042 suggested delivery of more than one active agent, however, CA '042 does not teach more than one superimposed layers containing adhesive or pile of the article as claimed in claims 19-26, 28-30, 35, 45, 46, 53, and 58.

US '581 teaches multilayered transdermal therapeutic system assembled from superimposed monolithic unites to obtain the finished device (abstract). The device comprises more than one therapeutic agent contained in different adhesive matrices to deliver mixture of therapeutic agents (col.5, lines 30-55). The multilayered device has improved reliability and is produced by manipulable steps (col.2, lines 33-38). Example of drugs to be delivered by the device anti-inflammatory drugs, ant-histaminic drugs, and vasodilators (col.5, lines 58-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises adhesive matrix and therapeutic agent wherein more than one active agents can be enclosed separate from one another in the article as disclosed by t CA '042, and provide the different active agent in more than one superimposed adhesive layers as disclosed by US '581. One would have been motivated to do so because US '581 teaches that

multilayered device has improved reliability and is produced by manipulable steps, and deliver mixture of beneficial therapeutic agents. One would have reasonably expected formulating article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises multiple layers comprises adhesive matrix and different therapeutic agent wherein more than one active agents can be delivered from improved reliable device.

8. Claims 12, 13, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA '042 in view of JP 04108710 ('710).

The teachings of CA '042 are previously discussed set forth in this office action.

However, CA '042 does not teach magnetizable particles in the therapeutic composition.

JP '710 teaches cosmetic in adhesive matrix comprising magnetizable particles that are capable of promoting of blood flow to the skin without causing inflammation to the skin (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises adhesive matrix and therapeutic agent as disclosed by CA '042, and add magnetizable particles to the active agent containing layer as disclosed by JP '710. One would have been motivated to do so because JP '710 teaches that the magnetizable particles are capable of promoting the blood flow to the skin without causing its inflammation. One would

have reasonably expected formulating an article comprising two outer layers and middle adhesive layer comprising magnetizable particles that promotes the blood flow to the skin without causing its inflammation.

Response to Arguments

9. Applicant's arguments filed 02/06/09 have been fully considered but they are not persuasive.

Claim 61, and Claims 12, 13, 19-26, 28-30, 35, 45, 46, 53, and 58

Applicant further argue that the rejection of these claims under § 103(a), based on '042 patent in view of Yoko, fails to establish a prima facie case of obviousness. Applicant hereby repeats the argument regarding claim 1. Applicant argues that Yoko is cited only for teaching of a "cosmetic in adhesive matrix comprising magnetizable particles", and fails to cure the deficiencies of the '042 patent. Therefore, the cited art does not disclose or suggest all of the recited features of independent claim 61, and fails to establish a prima facie case of obvious with respect to claim 61.

The examiner repeats the response as for claim 1 as set forth in this office action. CA '042 teaches the claimed composite claimed by claim 61, except for the magnetic particles. As applicant admits, Yoko is relied upon for the teaching of magnetizable particles in a cosmetic device. Combination of the references will teach the present invention as a whole as claimed by claim 61, so are dependent claims from claim 61. One would have been motivated to add magnetizable particles to the active agent containing layer because Yoko teaches that the magnetizable particles are

capable of promoting the blood flow to the skin without causing its inflammation. One would have reasonably expected formulating an article comprising two outer layers and middle adhesive layer comprising magnetizable particles that promotes the blood flow to the skin without causing its inflammation.

Applicant argues that Kochinke fails to cure the deficiencies of the '042 patent discussed above with respect to independent claims 1, 27, and 56, from which each of claims 19-26, 28-30, 35, 45, 46, 53, and 58 respectively depends.

The examiner hereby repeats the argument regarding claims 1, 27, and 56, and further argues that Kochinke is relied upon for the solely teaching of providing the different active agent in more than one superimposed adhesive layers. One would have been motivated to provide more than one active agent in more than one superimposed adhesive layers motivated by the teaching of Kochinke that multilayered device has improved reliability and is produced by manipulable steps, and deliver mixture of beneficial therapeutic agents. One would reasonably expected formulating article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises multiple layers comprises adhesive matrix and different therapeutic agent wherein more than one active agents can be delivered from improved reliable device.

These references (Yoko and Kochinke) show that it was well known in the art at the time of the invention to use magnetic particles in cosmetic compositions and

providing more than one active agent in superimposed layers. It is well known that it is prima facie obvious to combine two or more elements each of which is taught by the prior art to be useful for the same purpose in order to form a third composition or article which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80) 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Based on the disclosure by these references that the magnetic particles can be incorporated in cosmetic compositions and including different active agents in multiple layers of cosmetic article, an artisan of ordinary skill would have a reasonable expectation that a combination of these elements would also be useful in creating cosmetic composition or articles comprising magnetic particles and comprising more than one layer comprising different active agent in each layer. No patentable invention resides in combining old elements of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG